DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

March 21, 1997

The Honorable Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

I am writing to express concern about the position of the United States Patent and Trademark Office (PTO) on the patentability of Expressed Sequence Tags (ESTs), as presented by Acting Deputy Commissioner Laurence J. Goffney on February 14, 1997, at the meeting of the American Association for the Advancement of Science in Seattle.

From transcripts of his remarks and in follow-up discussions with my staff, it is our understanding that the PTO determined in October 1996 that ESTs could meet the statutory utility requirements based on their usefulness as probes for corresponding nucleotide sequences. On the basis of this determination, the PTO has begun the process of examining the more than 300 applications currently pending related to ESTs.

As a scientist and public health official, I am deeply concerned about this decision. In February 1994, following extensive discussions with scientists, industry representatives, and experts in patent law, the NIH determined that it was not in the best interest of the public health or science to pursue patents on partial or full gene sequences for which function and practical utility are unknown. At that time, I personally communicated this decision to key leaders in the U.S. and the international scientific communities. I enlisted the help of these individuals in educating biomedical research scientists on the importance of publishing and freely disseminating the results of early sequencing work to ensure both a growing body of scientific knowledge and the availability of novel therapies and diagnostics through commercialization of that knowledge. Over the past three years, scientists in academia and industry have benefited from an ever-growing public database due to their willingness to place their sequencing data in the public domain. The PTO decision, based on the new utility guidelines, will affect this ongoing research as it will once again call into question whether scientists can reasonably be asked to share early sequencing data.

Further, I am concerned that the ability to obtain a patent on a partial gene sequence, before the full sequence and substantive knowledge of biological function is obtained, will adversely affect the commercialization of new therapeutic technologies arising from these findings. We can expect a few companies to embark on the massive expenditure of time and resources required to bring biomedical products to market if there is a high likelihood that

claims could later issue from an EST or partial sequence patent application filed many years earlier. While the issues related to commercialization are within the purview of industry, a public health concern does arise if industry delays or refrains from developing and marketing these important technologies.

My staff has articulated these concerns in a letter to Mr. Goffney, which I have enclosed for your information and use. I am confident that the interaction between the PTO and the NIH on this important matter will ensure that the public investment in biomedical research will enhance the public health.

Sincerely,

/s/
Harold Varmus, M.D.
Director

Enclosure